



Alliance for Lupus Research

PREVENT. TREAT. CURE.

**ALLIANCE FOR LUPUS RESEARCH
TARGET IDENTIFICATION IN LUPUS APPLICATION
PROGRAM GUIDELINES**

Effective – October 15, 2015

**Letter of Intent Due – December 4, 2015
APPLICATION DUE DATE – January 25, 2016**

Applications will be administered by:

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Mission

*The mission of the Alliance for Lupus Research is to prevent,
treat and cure lupus through medical research.*

ALLIANCE FOR LUPUS RESEARCH: PROGRAM GUIDELINES

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<p style="text-align: center;">TARGET IDENTIFICATION IN LUPUS 2015 Alliance for Lupus Research Initiative</p>

DESCRIPTION OF TARGET IDENTIFICATION IN LUPUS PROGRAM

The Alliance for Lupus Research (ALR) is an independent, voluntary health agency formed to provide a concentrated effort for the prevention, treatment and cure of systemic lupus erythematosus (lupus or SLE). The purpose of the ALR Target Identification in Lupus (TIL) grants program is to fund highly meritorious and innovative research focused on the identification and scientific and/or clinical advancement of therapeutic targets that will lead to new therapies for the treatment of lupus. Lupus is a complex systemic autoimmune disease that can cause significant morbidity and mortality. At present, therapy for lupus is empiric and involves a variety of non-specific anti-inflammatory and immunosuppressive agents. While these agents are frequently beneficial, many patients do not respond adequately or experience significant side effects. This grant program has been established to develop new approaches to treat lupus more effectively and safely.

Program Goals: The goals of the TIL grant program are to: (1) characterize key steps in the pathogenesis of the disease that will allow for the development of new therapeutic agents; (2) promote basic and clinical research studies to identify and/or better characterize promising lead compounds for lupus treatment; and (3) support research that facilitates the clinical evaluation of innovative approaches to the prevention or treatment of lupus and its complications. This research is intended to be highly focused on lupus and, as such, should lead directly to knowledge that will facilitate drug discovery and/or testing of new treatments. These therapies may be used to treat systemic or organ-specific manifestations of lupus, although they may find applicability in the setting of other autoimmune or inflammatory illnesses. As the goal of this program is to advance the treatment of lupus, any research funded must be based on realizable goals for translation into therapeutic discovery programs. Targets can include small molecules, biologic agents, vaccines, gene therapy, as well as novel approaches in public health and risk reduction. The ALR particularly welcomes applications proposing research that will apply knowledge gained in other disease areas (e.g. cancer, metabolic diseases) to mechanisms relevant to lupus.

Eligibility Criteria: Individuals with doctoral degrees (MD, PhD, DO or equivalent) are eligible to apply. Scientific independence, as evidenced by direction of a research program, a publication record, or other experience that establishes scientific leadership is necessary to apply. The ALR does not impose geographic restrictions on its applicants. Investigators working anywhere in the world are eligible to apply. The ALR is willing to appropriately support research in industry or collaborations between academia and industry.

Relevance to the Mission of the Alliance for Lupus Research: The TIL grant program will fund research that will accelerate the development of new treatments of lupus. As such, these grants should be innovative in direction and utilize state-of-the-art techniques. Fundamental studies in genetics, immunology, cell biology and molecular biology to identify and characterize molecular systems must be oriented towards the development of drugs that would prevent and/or

ameliorate clinical signs and symptoms of lupus. These studies can be initiated or conducted in either humans or animals, although any work on animals must include a plan for extension and verification in patient populations. Studies working towards the identification or development of lead therapeutic compounds for lupus must provide a clear scientific rationale for the compound(s) under investigation, and a research plan that would allow for a definitive decision regarding the viability of the compound(s) as a therapeutic approach to lupus. Clinical studies to improve the ability to evaluate innovative therapies in lupus may focus on the development of systems or processes that enhance the ability to obtain reliable and timely answers to therapeutic questions in lupus.

TIL grants should lead to new insights into disease pathogenesis, advances in the development of innovative therapies under consideration for lupus, or improvements in the abilities to evaluate the outcome of lupus therapies. These proposals must demonstrate a strong orientation to the development and/or evaluation of new therapeutics. Thus, these grants differ from a conventional R01 mechanism where a translational goal is not essential to the success of the grant. Applications submitted for the TIL grant program must be relevant to the purpose and goals of the program.

The ALR has supported a large SLE genetics initiative. This initiative, led by a consortium of investigators, was designed to conduct a whole-genome association study in SLE. The ALR will only review TIL grant applications in genetics that do not duplicate the SLE Consortium initiative.

APPLICATION INSTRUCTIONS

Letter of Intent (LOI) : A non-binding letter of intent must be submitted by the investigator in advance of an invitation to apply for a grant. This letter should provide the proposed title of the research project and the name of the Principal Investigator. The letter must include a summary of the general theme and the potential future clinical ramification of the project future should it be successful. Submission of the LOI does not commit the investigator to submitting an application; however it is required to be submitted in order to have access to the full application. The main purpose of this letter is to assist the ALR's Scientific Advisory Board in determining whether the proposed subject matter of the proposal falls within the ALR's particular research goals during the upcoming funding year.

- LOIs should be submitted electronically through proposalCENTRAL no later than December 4, 2015 by 5 p.m. (EST). The submitted LOI must be approved by the ALR. The full application will become available once the LOI is approved. Detailed instructions for LOI submission are available in the Altum proposalCENTRAL website.

Application Information:

Each application should contain the following information (please log into Altum proposalCENTRAL for a detailed description of all forms to be completed and uploaded):

1. Lay Abstract: An abstract for a lay audience of the research plan that includes the application's long term objectives and specific aims. Investigators should highlight the relevance of the work to lupus. The abstract should not exceed 3000 characters.
2. Scientific Abstract: A technical abstract of the research plan that includes the application's long term objectives and specific aims. Investigators should highlight the relevance of the work to lupus. The abstract should not exceed 3000 characters.
3. Resubmission Statement (if applicable): Revised applications are required to include a resubmission statement that addresses the comments of the previous review, and explains how the application has been strengthened or modified. See *Resubmission Information* section for additional information.
4. Proposal Narrative: A research plan highlighting the significance and novelty of the work; describe the relevance of the project to the cause, cure, treatment or prevention of lupus and/or its secondary complications; highlight the relevance of the project to the goals of this Request for Applications; provide background information and rationale, approach and anticipated results for experiments that can be accomplished within three years.
5. Milestones: A list of milestones (the expected status of the project at various points in time). These milestones will be used to evaluate progress and to facilitate communication between the principal investigators and the ALR Scientific Advisory Board. The list of milestones should reflect the specific aims of the proposal and be presented within the context of a pathway for determining or evaluating a potential target for lupus treatment. A suggested format for listing these milestones is a table, listing by priority the goals, along with their respective expected dates of completion and measures. The milestones are part of the proposal narrative but are not included in the 10 page limit. See Instructions for Proposal Narrative in the electronic templates section.
6. Budget Detail and Summary: A budget for the project prepared in U.S. dollars. This information should be entered directly into the electronic application. The budget should be for three years. *Note*: This application is for three years of funding support. Third year of funding will be based on the successful completion of a non-competitive progress report and review by members of the ALR's Scientific Advisory Board. Applicants may apply for two years of funding, if preferred.
7. Budget Justification: A detailed justification for the budgetary requests. This information should be entered directly into the electronic application. The information in this section should be divided into two sections. The first section should include the following line items: personnel, consultant costs; equipment and supplies (both office and medical or laboratory). The second section should include all other line items including but not limited to: travel, patient care, other expenses, consortium and contractual costs. Each section should not exceed 2000 characters. Any additional information should be included as an appendix to the application.
8. Facilities & Equipment Description: A short description of the facilities and equipment available to support the project.

9. **Biosketch:** A standard NIH Biosketch for all key personnel working on the project. This should include a description of other financial support available to the applicant for his/her research endeavors. Applicants who are not based in the United States may submit a copy of their curriculum vitae.
10. **Assurances:** Appropriate institutional assurances regarding human subjects and animals as applicable.
11. **Other Support:** Applicants must include accurate and complete information regarding all other sources of grant support from the main PI (current and pending), including title, abstract, annual and total amount of the grant, inclusive funding period, and percent effort of the applicant. It is not necessary to include this information for all Key Personnel. This should also include a description of currently active support and all projects and proposals pending review and/or award whether or not financially and/or scientifically related to this application.
12. **Consultant/Co-Investigator/Collaborator Letters:** Optional, only submit if relevant to the application.
13. **Consent Forms:** If relevant, copies or drafts of all informed consent forms to be distributed to participants for signature in this study (or their legal guardians).
14. **Appendix Materials:** See instructions for appendix material allowed.
15. **Signed Cover Page:** The signed cover page should be uploaded electronically. Instructions will be available in Altum Proposal Central.

Supplemental Material: Applicants will have the opportunity to provide supplemental material (limited to 2 pages) related to their research project. Applicants will be notified by email as to the method of delivery and deadline date for receiving this information.

Restriction on Number of Applications: Only one application will be accepted per principal investigator in a grant cycle.

Resubmission Information:

- A resubmission is considered an application un-funded in one of the previous two TIL application cycles. An applicant who is unsuccessful in a competition may resubmit a similar revised application three times (the original, plus two resubmissions).
- If major changes are made to the application or if this is an entirely different/new project, the application should not be submitted as a resubmission. Reviewers for applications checked as resubmissions will be provided with the critiques from the previous application cycle.
- If you include changes to your original proposal, highlight the changes. Explain how the application has been strengthened or modified (additions, deletions, revisions).
- If the changes are so extensive as to include changes to most of the proposed Proposal Narrative, explain this exception here.

REVIEW PROCESS

Rating of Applications: Applications will be evaluated based on the following criteria:

- ✓ Relevance to the program goals of the ALR: prevention, treatment, or cure of lupus
- ✓ Feasibility will be evaluated based on the ability to accomplish the work proposed within a three year time frame and the likelihood that the work will:

- ✓ characterize key steps in the pathogenesis of the disease that will allow for the development of new therapeutic agents
- ✓ promote basic and clinical research studies to identify and/or better characterize promising lead compounds for lupus treatment
- ✓ support research that facilitates the clinical evaluation of innovative approaches to the prevention or treatment of lupus and its complications.
- ✓ Appropriate research design; originality and scientific rigor

Review/Notification: All grant applications will be peer-reviewed by the Study Section of the ALR. Results from that peer review will be forwarded to the ALR Scientific Advisory Board (SAB). The SAB will consider the recommendations from the Study Section, as well as review the existing ALR portfolio to determine which applications would complement existing grants or address an unfilled area of research. The SAB will submit their recommendations to the ALR Board of Directors. This Board will consider all the previous recommendations and will also provide a lay perspective. This perspective will include patients' concerns and expectations, as well as deliberations on the business aspect of funding the recommended grants. The ALR Board of Directors will make all final funding decisions. Notification of approval/disapproval will be made to applicants in June of 2016. All applications submitted will undergo a pre-review process. For applications receiving a full review, critiques containing the reviewers' comments and/or critiques will be provided within 3 months of the review date. (Applications not recommended for full review will not receive any written critiques). By applying, you are acknowledging your understanding that critiques may not be provided. The ALR does not provide scores or application's rank to applicants.

TERMS OF AWARD

Award Period: Grants will be awarded for a maximum of three years; funding decisions for the grants will be made by the ALR Board of Directors in the spring of 2016. If approved, the start date for the project will be July 1, 2016.

Third Year Funding: Support for a third year of funding will be based on the successful submission of a non-competitive progress report and review by members of the ALR's Scientific Advisory Board in the fall of 2016. Funding decisions for the third year will be made by the ALR Board of Directors in the late fall of 2016.

Amount of Award: Funding for the TIL award will be made for up to \$200,000 per year (for a maximum of three years - total amount up to \$600,000) including indirect costs. Funding for the third year is based on the successful submission of a non-competitive progress report. The award amount will be determined by the ALR's Board of Directors based on the results of the peer review process including recommendations from the ALR's Scientific Advisory Board. Applications with budgets totaling less than the maximum amount are strongly encouraged.

Award Guidelines: The ALR follows the U.S. National Institute of Health salary guidelines for Principal Investigators, Post-Doctoral Fellows and other applicable persons who will work on the project. The ALR does not allow award funds to be appropriated to the cost of tuition. All indirect costs or institutional overhead costs are not to exceed 8% of the total amount approved (excluding equipment).

Equipment: Title to all equipment purchased with ALR funds shall vest in the Sponsoring Institution provided that, for the duration of the research grant and for a period not to exceed sixty days from the termination date of the grant, the ALR may, at its option, direct the Sponsoring Institution to transfer title to a new Sponsoring Institution.

Laboratory Visits: As a condition of support, the Principal Investigator agrees that a representative of the ALR may visit the laboratory or other venue where the grant is being funded upon reasonable prior notification.

Dissemination of Information: To disseminate information about the ALR research program to our volunteers and the public, grantees are expected to occasionally give brief presentations of their research to professional audiences or the general public. All applicants are required to provide a summary of their research project in non-technical language. The summary should be brief and should explain the relevance of the project to lupus in such a way that lay advocates involved in the review process can evaluate the potential contribution of the project to the mission of the ALR.

Publications: It is expected that the results of research supported by the ALR shall be published as rapidly as possible in the open literature, consistent with high standards of scientific excellence and rigor. The responsibility for publication lies exclusively with the Principal Investigator (and his/her collaborators) and the result of any work supported by the ALR may be published without prior review of the ALR. Any publication arising in whole or in part from a research grant funded by the ALR shall acknowledge funding support by the ALR. As soon as a manuscript is accepted for publication (whether during the term of the grant or after it has expired) a copy of the publication along with the name of the journal and expected date of publication should be forwarded to the ALR. As soon as reprints are available, a copy of the reprint should be forwarded to the attention of the Research Administration Department in the ALR office.

Internal Revenue Service Information: Personnel compensated in whole or in part with funds from the ALR are not considered employees of the ALR. Institutions shall be responsible for issuing the appropriate IRS tax filings for all individuals receiving compensation from Grantor's funds hereunder, and shall be responsible for withholding and paying all required federal and state payroll taxes with regard to such compensation.

Scientific Conduct and IRB Approval: The ALR provides grant-in-aid support for research projects including those that may involve human subjects. ALR will not act as the Sponsor of any research as that term is defined by Food and Drug Administration nor take on any of the responsibilities of a Sponsor. *See* 21 C.F.R. §§ 312.3, 812.3. ALR does not provide management support for the projects that it funds and does not assume responsibility for the conduct of the investigation or the acts of the investigator or others since all persons undertaking the funded research are acting under the direction and control of the grantee institution and subject to the institution's medical and scientific policies. As a condition of receiving ALR grant funding for research, a Grantee institution and the investigator each agrees (i) to safeguard the rights and welfare of any individual who may participate as a human subject in any research

funded in whole or in part by ALR and (ii) to seek and obtain approval from Grantee's institutional review board, where human subjects are involved, and to comply with the provisions of 45 C.F.R. pt. 46 to the same extent as each would were the research funded by the National Institutes of Health ("NIH"), (iii) to comply with United States Department of Health and Human Services regulations or guidelines regarding financial conflicts of interest (*see* 42 C.F.R. pt. 50, subpt. F), recombinant DNA, biohazards, research misconduct (*see* 42 C.F.R. pt. 93), and vertebrate animals, all to the same extent as each would were the research funded by NIH; and (iv) such other federal regulations as may pertain to the particular research funded in whole or in part by the ALR grant.

As a condition of receiving ALR Grant, the awardees institution must also agree to indemnify and hold harmless ALR, its officers, directors, trustees, employees, and agents (each an "Indemnified Party") from and against any and all claims asserted against or losses incurred by an Indemnified Party arising out of or relating to the research funded by this Grant even if the aspect of the research giving rise to the claim or loss was not funded by the ALR. In the event that an Indemnified Party receives a claim subject to this indemnification provision then that Party shall tender his, her or its defense to the Grantee. In the event that the same counsel cannot, due to a conflict or potential conflict, represent the Indemnified Party, then the Indemnified Party shall select counsel of its own choosing and Grantee shall promptly pay for all reasonable legal fees and expenses as those fees and expenses are incurred.

Principal Investigator Assurance: All research grants funded by the ALR are subject to the terms and conditions outlined in this document and the funding letter. Deviations from the policies outlined in this document are valid only if made in writing and signed by an official of the ALR. Research performed under ALR grants is the sole responsibility of the Principal Investigator of that grant and the Sponsoring Institution. The Principal Investigator and Sponsoring Institution are both responsible for insuring that all research activities are conducted in a safe, responsible, and ethical manner.

Intellectual Property and Patent Policy: The ALR's policy on intellectual property and patent ownership will be shared upon request.

Other Terms and Conditions: The submission of this application to the ALR certifies that the organization named in this application is in compliance with all statutes, Executive orders, and regulations restricting or prohibiting U.S. persons from engaging in transactions and dealings with countries, entities, or individuals subject to economic sanctions administered by the U.S. Department of the Treasury's Office of Foreign Assets Control. The organization is aware that a list of countries subject to such sanctions, a list of Specially Designated Nationals and Blocked Persons subject to such sanctions, and overviews and guidelines for each such sanctions program can be found at <http://www.treas.gov/ofac>. Should any change in circumstances pertaining to this certification occur at any time; the organization is required to notify the ALR immediately.

Cancellation: Any grant may be terminated or cancelled by the ALR upon written notice to the Principal Investigator and responsible Administrative Official at the Sponsoring Institution if in the sole discretion of the ALR; (1) the Principal Investigator is unable to carry out the research for any reason; (2) the Principal Investigator or any member of his/her research team is found by an institutional investigation to have committed scientific misconduct or fraud; (3) the Principal

Investigator has failed to comply with any of the terms and conditions of this award; (4) the ALR concludes that the Principal Investigator has received overlap funding for the award or that the funds are not being used for the purposes originally outlined in the research protocol, or; (5) the IRB approval for the grant has been rescinded.

SUBMISSION INSTRUCTIONS AND DEADLINES

Letters of Intent (LOI): Must be submitted electronically through the Altum proposalCENTRAL website by December 4, 2015. Altum proposalCENTRAL can be accessed directly at <https://proposalcentral.altum.com>. Do not e-mail or mail any copies of the LOI to the ALR, only electronic submissions will be accepted. Once the LOI is approved the applicant will have full access to the application in proposalCENTRAL.

Applications: The electronic application must have the signatures of both the applicant and the representative of the applicant's institution included as an upload. These documents will complete the official application. All applications must be submitted electronically through the Altum proposalCENTRAL website by January 25, 2016. Altum proposalCENTRAL can be accessed directly at <https://proposalcentral.altum.com>. Instructions and application forms are available on the proposalCENTRAL website. Do not e-mail or mail any copies of the application to the ALR, only electronic submissions will be accepted. You must upload the signed title page as part of the application.

Deadlines: The receipt deadline for the non-binding LOI is December 4, 2015. The deadline for the Target Identification in Lupus grant application is January 25, 2016. The LOI and electronic application must be received by the close of business (5:00 PM EST) on the respective deadline dates.

October 15, 2015	TIL RFA Distributed
December 4, 2015	TIL Letter of Intent Due
January 25, 2016	TIL Grant Application Due
Spring 2016	Application Review Meeting
June 2016	Funding decision and notification to all applicants
July 1, 2016	Grant activation date

Late or Incomplete Applications: An application will not be reviewed if; (1) it is not submitted by the deadline; (2) is incomplete; (3) the principal investigator is ineligible; (4) it exceeds the page limit, or; (5) uses a printer font smaller than standard type size (Arial 11 pt). An application will be considered incomplete if it fails to follow the instructions or if the material presented is insufficient to permit an adequate review without the solicitation of a substantial amount of additional information. The principal investigator bears the responsibility for submission of a complete application by the designated deadline date.

Change of Application Status: Should your application status change after submission including a withdrawal of application, a change of address, etc. you should notify the research department via e-mail immediately at research.admin@lupusresearch.org.

CONTACT INFORMATION

ALR Contact Information: Questions concerning the application submission process, or the administration of TIL grant applications, should be directed to the ALR Research Administration Department at (212) 218-2840 or research.admin@lupusresearch.org.

Altum proposalCENTRAL Contact Information: For help with the electronic grant application process, please contact the help desk of ProposalCENTRAL by email at pcsupport@altum.com. You may also contact them by phone at 1-800-875-2562, extension 227.